Remarks/Arguments:

This is a reply to the office action of September 2.

Claim 20 stands rejected as obvious over Schwartz et al. in view of Swanson. Claim 20 requires that a hole, having a diameter greater than the width of the notch, be formed at each said end of the notch.

The prior art does not disclose placing holes at the ends of slits in a tube of the type now claimed, and none of the art suggests such a modification of the references.

The examiner did not rely on a reference, but instead reasoned that "It would further have been obvious to one of ordinary skill in the art that a slit with ... circular ends of larger diameter than width of said slit would relieve stress on a tube as is known in the mechanical art and would be used as a product design option in consideration of materials and manufacturing practices."

We request the examiner reconsider the rejection, in view of the attached declaration and the discussion below..

Hypotubes like the one used for this work are mounted on medical devices used for intravascular treatments (such as PTCA balloon catheters, for example). Different kinds of hypotubes, with different shapes and notches, can modify the mechanical characteristics of the finished device, affecting the device's overall performance during its intended use, and the clinical outcome for the patient. From a mechanical point of view, the clinical performance of a medical device which includes a hypotube requires that:

1. the device must have a good flexibility and trackability;
2. the device must have a good resistance to compressive and traction forces;

3. the device must have a good resistance to torque moment.

We enclose a Section 132 declaration of Achille Sina and Marco Miliani for the examiner's consideration. The declarants are employees of the applicant company Invatec. They performed a detailed finite element analysis of two tubes, one according to the invention and another identical one lacking the feature of a "hole, having a diameter greater than the width of the notch, is formed at each said end", as recited in claim 20.

The results reported in the attached declaration show significantly better performance for the "rounded notches" version of the hypotube, compared to the "simple notches" version. In particular:

1. The rounded notches give a better flexibility to the hypotube, since the local deformation of the "rounded-notches" version is higher than the one of "simple-notches" version, under the same boundary conditions (Ures (MAX) "roundednotches" = 0.110 mm ≥ Ures (MAX) "simple-notches" = 0.096 mm). This means that the hypotube with rounded notches is easier to bend than the one with simple notches, and this characteristic is experimentally related to a better trackability through the vascular anatomy.

2. The rounded notches give a better resistance to compressive and traction forces, since the Von Mises stress generated in the "rounded-notches" version is lower than the one generated in the "simple-notches" version (132.1 MPa vs. 142.8 MPa for traction; 132.1 MPa vs. 142.7 MPa for compressive forces). That is, under the same boundary conditions and forces applied proximally by the physician to the device, the hypotube with rounded notches generates a lower stress in the device, without reaching the yield point of the material, compared to the "simple-notches" version. This characteristic is experimentally related to a better resistance during insertion

(compressive forces) and retraction (traction forces) of the device into the vascular anatomy.

3. The rounded notches also give a better resistance to torque moment, since the stress generated in the "rounded-notches" version is lower than that generated in the "simple-notches" version (60.5 MPa vs. 78.8 MPa). Thus, under the same boundary conditions and torque moment applied proximally by the physician to the device, the hypotube with rounded notches generates a lower stress in the device, without reaching the yield point of the material, compared to the "simple-notches" version. This characteristic, in practice, produces better resistance during device positioning by the physician into the vascular anatomy.

We submit that the analysis reported by the Section 132 declarants demonstrate that the improvement recited in claim 20 produces a surprisingly superior product, and that this improvement would not have been obvious – except in retrospect – to a person of ordinary skill in the field of this invention at the time the invention was made.

Respectfully submitted,

/Charles Fallow/

Charles W. Fallow
Reg. No. 28,946

Shoemaker and Mattare, Ltd.
10 Post Office Road - Suite 100
Silver Spring, Maryland 20910

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